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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,257	12/14/2001	Jangbir S. Sangha	5006611-2	8707

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EXAMINER	
FREDMAN, JEFFREY NORMAN	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,257	SANGHA ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29,32-36,38,40-56,58-66,68-76,78-86 and 88-102* is/are pending in the application.

4a) Of the above claim(s) *7-25,40-55 and 96-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,26-29,32-36,38,56,58-66,68-76,78-86 and 88-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, 56, 57, 59 and 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Covalciuc et al (J. Clin. Microbiol. (1999) 37:3971-3974) as evidenced by Hardwood Products Company Quality Assurance letter, dated August 11, 1999.

Covalciuc teaches a kit for the collection of material containing DNA (see page 3971, column 2) comprising:

(a) a housing (see page 3971, subheadings "Throat swabs" and "Nasopharyngeal swabs" where the swabs are placed into a paper wrapper, which is a housing) containing at least one collection device for collection material containing DNA (see page 3971, subheadings "Throat swabs" and "Nasopharyngeal swabs", where Covalciuc teaches the use of Dacron or Rayon swabs purchased from Hardwood Products Company (HPC), Guilford Maine).

With regard to claim 56, the paper wrapper is a roughly tubular holder that permits retraction of the sample into the holder for sample storage, which in fact, was performed by Covalciuc (see page 3971, column 2).

With regard to claims 62-64, Covalciuc teaches the use of Dacron swabs which have some level of adhesion that is variable in it's binding (see page 3971, column 2).

Hardwood Products Company Letter, signed by William Young, states that HPC products are sterilized by ethylene oxide gas (see letter).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 56-58 and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricciardi et al (U.S. Patent 6,291,171) in view of Deragon et al (Nucleic Acids Research (1990) 18(2):6149).

Ricciardi et al teaches a kit for the collection of material containing DNA (see abstract and figure 1) comprising:

(a) a housing containing at least one collection device for collection material containing DNA (see figure 1 and column 2, lines 30-42).

Ricciardi expressly teaches that the swabs may be used for PCR amplification and that the swabs should be sterile (see column 2, lines 5-10).

With regard to claim 56, Ricciardi teaches a tubular holder, see figure 1, hole 30a, which is tubular shaped and which permits extension and retraction through the holder (see figure 1).

With regard to claims 62-64, Ricciardi teaches the use of Dacron swabs which have some level of adhesion that is variable in it's binding (see column 3, lines 36).

Ricciardi does not expressly teach how to sterilize the swabs for PCR amplification.

Deragon teaches, with regard to claims 2 and 3, that gamma radiation will suppress DNA contamination in PCR amplification reactions, permitting amplification of only the sample and not some previously present contaminant (see page 6149).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the sterilization technique of Deragon to create sterile swabs for the kit of Ricciardi since Ricciardi states "This is critical since the polymerase chain reaction (PCR) which is eventually used to analyze the DNA extracted is very sensitive to contamination from other surfaces, for example a table or counter top (see column 3, lines 53-57)", and Deragon teaches that treatment with gamma radiation will achieve sterility noting "Gamma irradiation provides one option for

the suppression of PCR ampification from trace amounts of contaminating DNA (see page 6149, column 1)."

6. Claims 1-6, 56-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricciardi et al (U.S. Patent 6,291,171) in view of Northview Biosciences Inc. (March 2001) (titled Sterility Assurance Compliance) (http://www.northviewlabs.com/pdf_docs/SterilityAssurance.pdf).

Ricciardi et al teaches a kit for the collection of material containing DNA (see abstract and figure 1) comprising:

(a) a housing containing at least one collection device for collection material containing DNA (see figure 1 and column 2, lines 30-42).

Ricciardi expressly teaches that the swabs may be used for PCR amplification and that the swabs should be sterile (see column 2, lines 5-10).

With regard to claim 56, Ricciardi teaches a tubular holder, see figure 1, hole 30a, which is tubular shaped and which permits extension and retraction through the holder (see figure 1).

With regard to claims 62-64, Ricciardi teaches the use of Dacron swabs which have some level of adhesion that is variable in it's binding (see column 3, lines 36).

Ricciardi et al does not teach modes of sterilization.

Northview Biosciences teaches sterilization of kits using a variety of equivalent techniques including ethylene oxide, gamma radiation and electron beam radiation (see page 2)

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to sterilize the kit and swabs of Ricciardi since Ricciardi states that the sterile swabs are used (see column 2, line 10) and since Northview Biosciences notes "Sterility is essential to the safety of many medical devices. Most single use devices are terminally sterilized by ethylene oxide gas or gamma or electron beam radiation (see page 2)". An ordinary practitioner would have been motivated to terminally sterilize the kit of Ricciardi in order to improve the safety of the device and to ensure that swabs, which would be placed within the oral cavity of human beings, would not contain any hazardous materials such as pathogenic microorganisms or viruses.

7. Claims 1-6, 26-29, 32-36, 38, 56, 58-66, 68-76, 78-86 and 88-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricciardi et al in view of Furcht et al (U.S. Patent 6,303,288) in view of Northview Biosciences Inc. (March 2001) (titled Sterility Assurance Compliance) (http://www.northviewlabs.com/pdf_docs/SterilityAssurance.pdf).

Ricciardi et al in view of Northview Biosciences Inc. teach the limitations of claims 1-6 and 56-64 as discussed above.

With regard to claims 76 and 86, Ricciardi teaches placement of the swabs in a protective pouch (see figure 1).

With regard to claims 32-35, 39, 68-71, 78-81, 88-91, Northview Biosciences teaches sterilization of kits using a variety of equivalent techniques including ethylene oxide, gamma radiation and electron beam radiation (see page 2)

Ricciardi et al in view of Northview Biosciences Inc. do not teach a device which has a rear surface that prevents collection of the DNA.

Furcht et al teaches, with regard to claims 26, 36, 38, 66, a device for the collection of material containing DNA (see abstract and figure 1) comprising:

A device for collecting material containing DNA that has a collection portion, (figure 3, reference number 32, which column 8, lines 54-67 identifies as a sample collection pad that is placed on a plastic support, reference number 31 (see column 8, lines 41-44), where the figure shows a front surface that is available for the collection of material containing DNA and a rear surface that is covered by plastic and is not available for DNA collection (see figure 3).

With regard to claims 27-29, Furcht teaches buccal scraping (see column 8, line 62). Further, these limitations do not impose any structural requirements on the product and simply represent intended uses of the product. As MPEP 2111.02 notes "Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." Here, no such structural difference currently exists.

With regard to claims 65, 72-75, 82-85, 92-95, Furcht teaches the use of FTA paper which inherently has some level of adhesion that is at least slightly variable in it's binding (see column 8, line 58).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the device of Furcht in the kit of Ricciardi since Furcht notes "This application of the microcantilever based sensor offers superior sensitivity, specificity and utility in an integrated MEMS system format (see column 12, lines 7-10)." Furcht further motivates the use of FTA paper by noting "DNA extractions on FTA^{tm} paper have demonstrated significant ease in use and reduced cost in performing routine clinical molecular genetic testing (see column 2, lines 53-56)." Motivation to sterilize the device is provided by Northview Biosciences which notes "Sterility is essential to the safety of many medical devices. Most single use devices are terminally sterilized by ethylene oxide gas or gamma or electron beam radiation (see page 2)". An ordinary practitioner would have been motivated to use the device of Furcht in the kit of Ricciardi since the device will improve sensitivity, specificity and utility and reduce labor costs and specimen sizes (see column 12 and column 2, lines 21-38). Further, an ordinary pracititioner would have been motivated by Northview biosciences to sterilize the kit in order to improve the safety of the device and to ensure that swabs, which would be placed within the oral cavity of human beings, would not contain any hazardous materials such as pathogenic microorganisms or viruses.

Response to Arguments

8. Applicant's arguments filed May 13, 2004 have been fully considered but they are not persuasive.

Applicant argues, essentially, that lower doses of the sterilizing reagents are necessary in order to eliminate DNA contamination as versus complete sterilization.

This argument does not distinguish the claimed invention, which is a product, because a product which is sterilized has also eliminated all of the DNA contamination. Therefore, the cited prior meets the claimed invention.

Essentially, the new clause "comprising an effective amount of an agent for disabling DNA from interfering with subsequent specimen's specific DNA analysis" has no structural impact on the claim. It does not place an upper limit on the amount of reagent used. Any amount which will function will meet the claim. Since Applicant's own response accepts the argument that the cited sterilization references will disable DNA, but simply is overkill for this purpose, this argument fails to overcome the prior art rejections. As MPEP 2113 makes clear, product by process claims are only limited by the structure implied by the steps, not the steps themselves. Since the prior art meets the structure required by the claims, the prior art remains applicable.

If Applicant means to argue that the device is sterilized at some other point, then Applicant is failing to appreciate the breadth of the claim. The term "housing" may refer to a box in which components are put, but it may also simply refer to the paper covering on a swab. Both of those elements can be termed "housing". So if the swab is the collection device andthe paper covering into which the swab is put is the housing, then sterilization of the paper covering after putting the swab in meets the claim.

With regard to the 103 rejections, these references make it clear that sterility is desired and that removal of contaminating DNA is desired, which directly suggests application of the various sterilization methods to the sample collection devices to eliminate contaminating DNA which may interfere with PCR.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1637